

Directive

9180.66

6-8-00

ZEARALENONE TESTING

1. PURPOSE

This directive provides information concerning the testing for Zearalenone as an official criteria factor under the United States Grain Standards Act (USGSA), as amended.

2. BACKGROUND

Zearalenone is the generic name for a mycotoxin that is produced by several species, of fungus (*Fusarium*), the most notable of which is the *Fusarium roseum*. Species of *Fusarium* are common and widespread in nature and are found worldwide on most economic crops. *Fusarium* infection and production of zearalenone are most notable on corn, wheat, sorghum, oats, and barley.

Historically, zearalenone has been found at low levels in corn, barley, oats, sorghum, corn meal, hay, silage, and commercial animal rations in the United States. A combination of the fungus strain, high moisture content, and a period of relatively high temperature (as in ears of corn before harvest) followed by a period of low temperature (as in corn stored on the ear in cribs) favor the production of the toxin.

3. REPLACEMENT HIGHLIGHTS

This directive supersedes FGIS Program Notice 97-11, "Zearalenone Test Services", dated April 25, 1997.

4. TESTING SERVICE

The Federal Grain Inspection Service (FGIS) provides a testing service for zearalenone in corn and wheat as official criteria. FGIS is providing the testing service using direct competitive enzyme-linked immunosorbent assay (ELISA) test kits capable of detecting zearalenone between 100 - 1,000 parts per billion (ppb). Quantitation limits are between 250 - 1,000 ppb.

Testing is performed by the Analytical, Reference, and Testing Services (ARTS) Branch of the Technical Services Division (TSD) in Kansas City, Missouri.

Zearalenone test results are not reported to the Food and Drug Administration because action limits are not established at this time.

5. TYPES OF SERVICES

Three types of Zearalenone testing services are available as follows:

- a. Submitted Sample Service - Analysis based on a sample submitted by the applicant for service.
- b. Official Sample-Lot Service - Analysis based on an official sample obtained by official personnel and analyzed by the ARTS Branch.

Shiplots are tested on the basis of a composite sample. Sublot testing is available in addition to, or in lieu of, composite sample testing. Individuals requesting zearalenone testing service must specify composite and/or sublot sample testing basis.

Acceptable quality will be based on the sublot/composite sample result(s) as compared to the contracted maximum specification, if required.

- c. Warehouse sample - Lot Inspection Service - Analysis based on an official sample obtained by a licensed warehouse sampler and analyzed by the ARTS Branch.

6. REVIEW INSPECTIONS

Sections 800.125 and 800.135 of the USGSA permit a review (reinspection, appeal, Board appeal) inspection on either official grade/factors or official criteria. When requested, a review inspection for official grade or official factor and official criteria may be handled separately even though both sets of results are reported on the same certificate.

Review inspection services for zearalenone are provided on either a new sample or the file sample in accordance with the regulations. Board appeal inspection services are limited to the analysis of file samples.

7. SAMPLE PREPARATION

Samples shall be representative of the lot and meet the following size requirements:

- a. Export Sublot Testing - 10 pounds per sublot.
- b. Unit Train Sublot Testing - 10 pounds per sublot (proportionately sampled from all carriers forming the sublot).
- c. Individual Carrier Basis (railcars) - 3 pounds from each carrier.
- d. Individual Carrier Basis (trucklots) - 2 pounds from each carrier.

- e. Individual Carrier Basis (bargelots) - 10 pounds per bargelot.
- f. Submitted Samples - minimum 1 pound.
- g. Composite Samples - 10 pounds (proportionately sampled from the lot).

Grind the entire sample (dockage free for wheat) and submit a 1/4 portion to the ARTS Branch for testing. Retain the remaining ground portion as a file sample.

Note: To obtain a 1/4 portion, set the Romer Mill to automatically divide the sample to the appropriate size, or grind the sample and divide it to the proper size using a riffle divider. Samples ground on non-Romer Mills must be divided through a riffle divider to obtain equal representative portions. **Do not** “scoop” a portion of the sample for analysis.

8. MAILING INSTRUCTIONS

When sending samples for zearalenone testing, write the words “ZEARALENONE TESTING” in the remarks section of the grain sample ticket and on the back of the mailing tag. Address the mailing tag to the ARTS Branch.

9. CERTIFICATION

Applicants for service can request results reported on a quantitative or qualitative basis. Quantitative test results are reported to the nearest whole number in ppb, or nearest hundredth in parts per million (ppm).

Certificate the results in ppb or ppm as requested by the applicant. To convert ppb to ppm, divide the ppb result by 1,000.

Results may be reported on a separate certificate or on the certificate for grade at the applicant's option. When zearalenone is certified for export shipments, date the certificate the date loading was completed. For domestic shipments, date the certificate with the actual date that the results are received.

- a. For qualitative service, certificate results as being equal to or less than a threshold (e.g., 500 ppb, 0.50 ppm) or exceeding the threshold by using the following statements:

“Zearalenone exceeds (specified threshold) ppb/ppm.”

“Zearalenone equal to or less than (specified threshold) ppb/ppm.”

- b. For quantitative service, certificate test results between the lower (250 ppb) and the upper (1,000 ppb) quantitation limits to the actual ppb/ppm.

“Zearalenone (record actual result) ppb/ppm.”

Results below 250 ppb (0.25 ppm) or exceeding 1000 ppb (1.0 ppm) are certified as less than / greater than (as applicable) the quantitation limits.

"Zearalenone does not exceed (250 ppb) (0.25 ppm)."

"Zearalenone exceeds (1,000 ppb) (1.0 ppm)."

10. RESPONSIBILITIES

- a. Field Offices - Field offices sending samples to TSD are responsible for certification of the lot and billing the applicant for service.
- b. Official Agencies - Official agencies sending samples to TSD for testing are required to certificate the lot and bill the applicant for service through their typical billing procedures.
- c. ARTS Branch - The ARTS Branch is responsible for performing the test and reporting the results to the field office/official agency that sent the sample for analysis.

The ARTS Branch is also responsible for billing the applicable test fee to official agencies that send samples for zearalenone testing.

For samples that are submitted directly to the ARTS Branch for testing, the ARTS Branch will be responsible for testing, certification, and billing.

/S/ David Orr

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